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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,180	CHEN ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6/02& 8/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election and Amendment filed August 1, 2003

Applicant's election without traverse of the invention of Group I filed August 1, 2003, is acknowledged. Applicant's cancellation of claims of the original claims 1-52 and the presentation of the new claims 53-75 in the Amendment filed August 1, 2003, is also acknowledged and, because the claims 53-75 correspond to the subject matter of the elected Group I, all are examined herein.

Claim Objections

Claim 56 is objected to because of the following informalities: Claim 56 recites a dependency to claim 5, a claim that has been cancelled, where Applicant actually intended to describe a dependency from claim 53. Claim 53 erroneously recites, at line 11, the term "complimentary" where the standard usage in the relevant arts requires instead the recitation of "complementary". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 53-75 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

A claimed invention must posses a specific, substantial and credible *in vitro* or *in vivo* utility, but the instant application cannot identify any specific, substantial, utility for the invention described by claims 53-75 known to the inventors at the time the application was filed. It is agreed that polynucleotides encoding polypeptides having the amino acid sequences described by clauses (a)-(c) of claim 53 as well as claims 54, 55 and 57-59 encode a polypeptide that shares a significant degree of amino acid sequence homology with other, prior art, mammalian serpins. Yet all of the new claims

53-75 lack utility because there is no disclosure in the specification of any specific *in vitro* utility for the polypeptide product encoded by the polynucleotides of clauses (a)-(d) of claim 53, or an *in vitro* utility for their complements of clause (d) of claim 53, nor any disclosure of a specific *in vivo* utility for a polypeptide product encoded by the polynucleotides of clauses (a)-(d) of claim 53, or an *in vivo* utility for their complements of clause (d) of claim 53. While the specification proposes, at pages 4-8 and 25-32, potential uses for a claimed polynucleotide and the encoded LSI-01 polypeptide as well as various assays and processes for determining its native biological function, nowhere does the specification disclose that the native LSI-01 polypeptide has the ability to inhibit the proteolytic activity of any specific protease or any specific serine protease. While the alleged utilities are substantial, none are specific to the disclosed, native, LSI-01 polypeptide or a polynucleotide that will encode it. A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Mere allegations of a prospective, potential, utility cannot rise to the level of a credible assertion of a specific *in vivo* utility that is substantial. Indeed, the specification's diffuse assertions indicate the contrary, that Applicant knew no specific utility for either a native LSI-01 polypeptide encoded by claimed polynucleotides at the time the application was filed that would permit an immediate use by the public of a disclosed polynucleotide or any use by the public of an expression vector or host cell comprising a disclosed polynucleotide. The recitations of claims 69, 71, 73 and 75 compound the problem of lack of the utility where they expressly exclude the utility alleged in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-75 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 68-75 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to exemplify or describe the preparation of variants of the LSI-01 serpin having the amino acid sequence set forth in SEQ ID NO:2 where the amino acid sequence is altered by any amino acid substitution in any of the eight amino acid sequence regions recited in claims 68-75. Instead, the specification discloses, between pages 46-52, the preparation of variants of the LSI-01 serpin having the amino acid sequence set forth in SEQ ID NO:2 where one or more amino acids are deleted, in contiguous arrays, within the eight amino acid sequence regions recited in claims 68-75. Thus, peptide regions within the overall amino acid sequence of SEQ ID NO:2 that are represented by the sequence of SEQ IDs NOs:24-31 may be altered by deleting one or more amino acids, so long as the deletions are contiguous, rather than interspersed, in any of the regions. The specification further fails to identify any amino acid sequence alterations within the eight regions recited in claims 68-75 that result in the abolition of "serpin activity" - the ability to inhibit the proteolytic activity of a serine protease - and it is not clear how any amino acid sequence alteration within the peptide regions that contribute to the heparin binding region identified in claims 70 and 71 could be expected to influence, let alone abolish, "serpin activity" of the native LSI-01 serpin having the amino acid sequence of SEQ ID NO:2. The specification has no teaching or suggestion

that implicates the heparin binding region identified in claims 70 and 71 in the inhibitory activity of the native LSI-01 serpin. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. §112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification furnishes no relevant identifying characteristics of serpin variants that have amino acid substitutions with the eight regions identified in claims 68-75 that would permit the artisan, or the public, to distinguish those that lack "serpin activity" from those that retain "serpin activity, nor does it provide any characteristic permitting a correlation between undisclosed amino acid substitutions in any of the eight regions identified in claims 68-75 and a likelihood of loss, or retention, of "serpin activity", particularly where no regions recited in claims 70 and 71 are disclosed to contribute to the undisclosed, native, "serpin activity" of the LSI-01 polypeptide.

The Court of Appeals for the Federal Circuit held that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might achieve if one had made that invention". *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Indeed, the claims rejected herein are, like the claims invalidated by the appellate panel in *University of California v. Eli Lilly*, designed to embrace other, as yet unknown, human serpins. Nothing demonstrates that, at the time the specification was filed, Applicant was "able to envision" enough of the structure of any undisclosed serpin variant to provide the public with identifying "characteristics [that] sufficiently distinguish it . . . from other materials". *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). The specification's

treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the structures of the variant serpins of claims 69, 71,73, and 75 that are no longer able to inhibit serine proteases, generally, from those variant serpins of claims 68, 70,72, and 74 that retain the ability to inhibit serine proteases.

Claims 53 and 60-75 are rejected under 35 U.S.C. § 112, first paragraph, because the specification is not enabling for isolated polynucleotides "encoding the LSI-01 polypeptide as encoded by the cDNA clone contained in ATCC Deposit No. PTA-2766", for vectors and host cells comprising same, for polynucleotides comprising same and encoding fusion polypeptides, nor for any polynucleotides encoding variants of the LSI-01 polypeptide as encoded by the cDNA clone contained in ATCC Deposit No. PTA-2766. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and use the invention commensurate in scope with these claims.

Claims 53 and 60-75 rely, in part, upon deposit of a specific biological material thus present an issue of enablement because the specification does not disclose that the claimed biological material, the "the cDNA clone contained in ATCC Deposit No. PTA-2766" is freely available to the public, either currently or upon the issuance of a patent having the claimed biological materials as subject matter. Deposits under the terms of the Budapest Treaty are, in themselves, insufficient to satisfy 37 CFR §§1.805-1.807 unless they are disclosed on the record to be freely available to the public should a U.S. patent issue on the instant application. See, *Ex parte Hildebrand*, 15 USPQ2d 1662, 1664 (1990) (restrictions must "be irrevocably removed upon the issuance of [a] patent" since Rule 9.2 of the Budapest Treaty contains a residual requirement of secrecy). See also, MPEP §608.01(p)(C)(3). Application of 37 CFR §1.801, et seq., to any deposit, including Budapest Treaty deposits, requires that an enabling disclosure based upon such a deposit be provided by submission of a declaration or averment, either by the **assignee** or the **attorney of record** over his or her signature and registration number, that gives these two assurances:

1) that all restrictions on the availability to the public of the deposited material

identifies a specific serine protease with which abolition, or retention, of serpin activity resulting from amino acid substitutions might be determined and the specification provides no basis for such an amendment. Mere sequence perturbation cannot enable the design and preparation of polynucleotides encoding a myriad of divergent serpins yet provide the public with a nucleotide sequence encoding a polypeptide that retains its native serine protease inhibitory activity, or has no such activity for any serine protease.

It is well settled that 35 U.S.C. §112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (recognizing and applying the "*Forman*" factors). Cf., *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (citing eight factors relevant to analysis of enablement). The standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970) (scope of enablement varies inversely with the degree of unpredictability of factors involved in physiological activity of small peptide hormone); **see also**, *Ex parte Maizel*, 27 USPQ2d 1662, 1665 (Bd. Pat. App. & Int. 1992) (functional equivalency of divergent gene products not supported by disclosure only of a single B-cell growth factor allele). The Federal Circuit approved the standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997). Applying the "*Forman*" factors discussed in *Wands*, ***supra***, to Applicant's disclosure, it is apparent that:

will be removed, and,

2) that the viability of the deposits will be maintained,

both for the duration of the patent term or for a period of twenty years in accordance with 37 CFR §§1.805-1.807. See, MPEP §§ 2405-2411.05, wherein the latter section requires an amendment to the specification introducing specific information concerning a deposit of biological materials where necessary to provide a complete record thereof. Such an amendment does not constitute new matter.

Claims 68-75 are rejected under 35 U.S.C. § 112, first paragraph, because the specification is not enabling for any embodiment of a polynucleotide that encodes a polypeptide having an amino acid sequence that diverges from the amino acid sequence of SEQ ID NO:2 as described by clauses (a)-(c) of claim 53 by amino acid substitutions in any of the eight regions recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and use the invention commensurate in scope with these claims.

Claims 68-75 contemplate arbitrary amino acid substitutions within regions of SEQ ID NO:2 corresponding to peptide sequences of SEQ IDs NOs:24-31 that result either in a loss of "serpin activity" - the ability to inhibit proteolytic activity of a serine protease - or in retention of "serpin activity". But the specification does not teach the artisan seeking to practice the claimed invention the nature of the serpin activity the LSI-01 polypeptide might have, if any, so that the artisan can know when a variant of claims 68, 70, 72 and 74 is made or, conversely, know when a variant of claims 69, 71, 73 and 75 is made. Indeed, the specification fails to suggest how the artisan might entirely abolish whatever serpin activity the LSI-01 polypeptide might possess so that the artisan can make variants of claims 69, 71, 73 and 75 by introducing amino acid substitutions in order to meet their functional limitation: "does not have serpin activity". As noted in the rejection above for lack of an adequate written description, the specification teaches no amino acid substitutions that can alter whatever general serine protease inhibitory activity the LSI-01 polypeptide might have and claims 69, 71, 73 and 75 require that any such activity be lost to any and all serine proteases. Claims 68-75 state no limitation that

a) the specification lacks adequate, specific, guidance for altering the amino acid sequence of the protease inhibitor of SEQ ID NO:2 to abolish protease inhibitor activity to serine proteases generally or to retain protease inhibitor activity with respect to any particular serine protease,

b) the specification lacks working examples wherein the amino acid sequence of the protease inhibitor of SEQ ID NO:2 is altered to achieve an inability to inhibit serine proteases generally, or to retain an ability to inhibit any particular serine protease, and,

c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such alteration.

Thus the scope of subject matters embraced by the phrases, "has serpin activity", and, "does not have serpin activity", is unsupported by the present specification even if taken in combination with teachings available in the prior art of record.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-75 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 is indefinite in reciting "including the start codon" at the close of clause (a) because this recitation is, at best, superfluous, and at worst is ambiguous because it suggests that a polynucleotide must "includ[e] the start codon" even though the amino acid positions recited already require that a polynucleotide comprise the disclosed start codon. Claim 53 is further indefinite in reciting "minus the start codon" at the close of clause (b) because this recitation is, at best, superfluous, and at worst is ambiguous because it suggests that a polynucleotide must exclude the start codon even though the amino acid positions recited already require that a polynucleotide exclude the disclosed start codon. Claim 53 is additionally indefinite in parenthetically reciting "(antisense") because the term is ambiguous where it does not further define Applicant's intended, full-length, complementary sequences and instead suggests further, non-coding, nucleic acid sequence elements commonly used in preparing antisense constructs. Claims 54-

75 are included in this rejection of claim 53 because they fail to independently resolve the ambiguities of claim 53 from which they depend.

Claim 67 is indefinite because the specification discloses at, e.g., page 2, that the polypeptide having the amino acid sequence of SEQ ID NO:2 is a serpin, an inhibitor of serine protease activity, but the claim improperly describes this polypeptide as having "serine protease" activity. Instead, Applicant may have intended to describe the serpin of SEQ ID NO:2 as having **inhibitory activity for serine proteases that cleave at the basic amino acids arginine and lysine**, see page 11, line 30, and page 23, lines 9-11, of the specification. Claims 68-75 mistakenly recite subject matters that exceed the scope of claim 53 from which they depend where the preamble of claim 53 does not permit polynucleotides of clauses (a)-(d) of the claim to encode polypeptides that comprise any amino acid substitutions in the regions of SEQ ID NO:2 recited in claims 68-75. Claims 68-75 are further indefinite because claims 68, 70, 72 and 74 recite "has serpin activity", and because claims 69, 71, 73 and 75 recite "does not have serpin activity", but no claim states any particular "serpin activity" so that the artisan and the public seeking to determine the scope of these claims and the specification provides no particular disclosure that will permit a specific determination of the meaning of "serpin activity" with which these claims might be construed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> e) the invention was described in-
>
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

Claim 70 is rejected under 35 U.S.C. § 102(e)(1) as being anticipated by Ni et al., U.S. 2002/0160491 and WO 2001/55390, both made of record herewith.

The published U.S. application of Ni et al. ('091) is discussed herein rather than the identical PCT publication of Ni et al. as both are based on a U.S. provisional application filed ten months before the 14 November 2000 priority date for the instant disclosure. Ni et al. disclose a polynucleotide encoding a human serine protease inhibitor having an amino acid sequence corresponding to the 435-amino acid sequence of the LSI-01 serpin set forth in SEQ ID NO:2 herein that comprises a relative amino acid substitution at position 310, i.e., I310V. See, SEQ IDs NOs:1 and 5 of Ni et al. Even though the polynucleotide of SEQ ID NO:1 of Ni et al. encodes a serpin comprising further relative amino acid substitutions beyond the substitution at position 310 of their SEQ ID NO:2, e.g., the relative amino acid substitutions L236P, Q254H, and A348V, the disclosure of Ni et al. meets limitations of claim 70 herein for a substitution between positions 306 to 315 of SEQ ID NO:2 herein and the relationship between the subject matters of claims 68-75 and claim 53 from which they depend is ambiguous, where they embrace a scope exceeding that of claim 53, thus cannot exclude the disclosure of Ni et al.

Claim 70 is rejected under 35 U.S.C. § 102(e)(1) as being anticipated by Sudhiras et al., WO 2001/55390, made of record with Applicant's Information Disclosure Statement filed June 17, 2002.

Sudhiras et al. disclose a human NOV2 nucleic acid sequence encoding "a member of the serpin family", page 10, line 33, a polynucleotide encoding a human serine protease inhibitor having an amino acid sequence corresponding to the 435-amino acid sequence of the LSI-01 serpin set forth in SEQ ID NO:2 herein that comprises a relative amino acid substitution at position 310, i.e., I310R. See, SEQ IDs NOs:3 and 4 at page 10 of Sudhiras et al. Even though the polynucleotide of SEQ ID NO:3 of Sudhiras et al. encodes a serpin comprising further relative amino acid substitutions beyond the substitution at position 310 of their SEQ ID NO:4, e.g., the relative amino acid substitutions L236P, Q254H, and A348V, the disclosure of Sudhiras et al. meets

limitations of claim 70 herein for a substitution between positions 306 to 315 of SEQ ID NO:2 herein and the relationship between the subject matters of claims 68-75 and claim 53 from which they depend is ambiguous, where they embrace a scope exceeding that of claim 53, thus cannot exclude the disclosure of Sudhiras et al.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
May 11, 2004